Exhibit 46

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

****

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

MDL No. 2875

Civil No. 19-2875 (RBK/JS)

****

THIS DOCUMENT APPLIES TO ALL CASES

HON ROBERT B. KUGLER

****

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

Remote Videotaped via Zoom Deposition of JUCAI GE, held at the location of the deponent, commencing at 7:04 a.m. China Standard Time, on the 26th of May, 2022, before Maureen O'Connor Pollard, Registered Diplomate Reporter, Realtime Systems Administrator, Certified Shorthand Reporter.

– – –

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Videographer: Judy Diaz

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P R O C E E D I N G S

THE VIDEOGRAPHER: We are now on the record.

My name is Judy Diaz. I'm the legal videographer for Golkow Litigation Services.

Today's date is May 26, 2022, and the time is 7:04 a.m.

This remote video deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation MDL, for the United States District Court, District of New Jersey.

The deponent is Jucai Ge.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All counsel will be noted on the stenographic record.

The court reporter is Maureen Pollard, and will now swear in the

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interpreter and the witness.

_ _ _

YANG SHAO, Interpreter, having been duly remotely sworn to translate the questions and answers to the best of his ability, translated as follows:

_ _ _

JUCAI GE, having been duly remotely identified and sworn, was examined and testified as follows through the interpreter:

EXAMINATION

BY MR. SLATER:

Q. Good evening.

A. Good evening.

Q. I guess it's good morning for you.

A. That's correct. It is morning here.

Q. We're going to take your deposition now. You know that, right?

A. I understand that.

Also, I'd like to express my appreciation to Adam for postponing this

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deposition by a month. Originally I was supposed to be quarantined for a month. So thank you for your understanding.

Q. You're welcome. I've never been thanked by a witness before. This is the best night of my life.

A. Thank you.

Q. I hope that you'll thank me at the end also.

A. I hope so, too. I will do my best to work with you.

Q. You understand as you just -- rephrase.

You just took an oath to tell the truth. You understand you must be truthful in answering all questions in this deposition, correct?

A. That is correct. That is for sure.

MR. SLATER: Chris, let's put up the deposition notice, please.

(Whereupon, ZHP Exhibit Numbers 456A and 456B were marked for identification.)

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BY MR. SLATER:

Q. This is the deposition notice for today's deposition.

Have you seen this document?

A. Yes, I've seen it before.

MR. SLATER: Let's go to Exhibit Number 2, the response to the deposition notice.

BY MR. SLATER:

Q. Have you seen this document, the response to the deposition notice?

A. I've also seen this before.

MR. SLATER: We can take that down.

MR. GEDDIS: Adam, just for the record, it's -- Exhibit 456A is the English dep notice; 456B is the Chinese translation, and then obviously so on for the next document.

MR. SLATER: Okay. So the second exhibit is 457A and 457B?

MR. GEDDIS: Yes.

MR. BERNARDO: Oh, I'm sorry. So the system is that each English

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version is the A and each Chinese version is the B, and they get the same number?

MR. GEDDIS: Yeah, that's what we've been doing in the past.

MR. BERNARDO: Thank you.

BY MR. SLATER:

Q. Did you prepare to testify in this deposition?

A. That is correct. I've done a lot of work in preparation for today's deposition in order to answer the related questions.

Q. Can you estimate how much time you spent preparing?

A. It was sometime in March that I received the deposition notice that I would testify as the representative of the company on certain topics, so I spent a lot of time to be familiar with all those topics.

And also I would communicate with people and review related documents. Every day I would spend from six to ten hours doing that, except for the two days I spent

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on my way here.

Therefore, every day I have been spending six to ten hours a day to be familiar with the topics and to communicate with people.

Q. And that is since March, when you first were told about the deposition?

A. Essentially, yes.

Q. Do you know what day in March that was, approximately or exactly?

A. I do not recall the exact date. All I can recall is that it was sometime before the Chinese Memorial Day. After that, I've been very busy reviewing the documents and communicating with people.

Q. What day is Chinese Memorial Day?

A. April 5th.

Q. We were advised that you interviewed a number of people to help you prepare, is that correct?

A. I don't quite get your question. However, once I was notified that I would represent the company to attend this

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deposition, I first approached my attorney or attorneys to have a better understanding of the topics. Then I approached related people and communicated with them, and I also reviewed the related documents.

Q. As part of your preparation, did you speak with Min Li? Yes or no.

A. Yes, I did.

Q. As part of your preparation, did you speak with Jinsheng Lin?

A. Yes, I did.

Q. As part of your preparation, did you speak with Peng Dong?

A. Yes, I did.

Q. As part of your preparation, did you speak with Linda Lin?

A. Yes, I did.

Q. As part of your preparation, did you speak with Hai Wang?

A. Yes, I did.

Q. As part of your preparation, did you speak with Lewis Chodosh?

A. Yes, I did.

Q. Did you speak with anybody else

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to help you prepare for this deposition?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: Are you referring to the preparation for this deposition in general without being specific for any topic?

BY MR. SLATER:

Q. I don't understand your question.

A. As for the people you just mentioned, I mainly communicate with them.

Q. Is there anybody else that you spoke with to help you prepare to testify in this deposition?

A. When it comes to issues like English, I did communicate with people from the QA department.

I also communicated with people such as Wei Cheng, spelled as W-E-I, last name C-H-E-N-G, on topics like responses.

Q. When you say you spoke with people in the QA department regarding English, what do you mean by that?

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A. Because I'm poor in English, and many documents, on the other hand, are in English. So I approached the people in the QA department and asked them to help me translate. They had to help me find related documents and then do the translation. That is because, indeed, my English is really poor.

Q. When did you speak to Lewis Chodosh?

Let me reask the question. When did you speak with Lewis Chodosh?

A. I don't recall the exact time. However, since he is based in the US, we were scheduled to have a meeting on a certain evening.

Q. Why did you speak to Lewis Chodosh?

A. That was because I read a report of the impact of NDMA or NDEA on health written by Dr. Chodosh, so I wanted to communicate with him regarding that report.

MR. SLATER: Chris, let's mark the -- put up the binder, and you can

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let us know what exhibit number it is.

MR. GEDDIS: It's Exhibit 458. I'll open it in one second.

(Whereupon, Exhibit Numbers ZHP-458A and ZHP- 458B were marked for identification.)

MR. GEDDIS: Do you want it in Chinese or English on the screen?

MR. SLATER: You know, I just really want the first page, just so we can identify it. The English is fine.

BY MR. SLATER:

Q. This is Exhibit 458A, and it's the table of contents for a binder we were provided.

Is that a binder that you reviewed?

A. Not only did I review all the documents listed here; I also reviewed other documents, simply because these documents are quite related to this case. I list those documents here.

Q. Did you compile the binder yourself?

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A. I compiled the Chinese version of the documents, and I got help for the translation for the English version, because I did not do the translation myself. I only compiled the Chinese version of the documents.

Q. Item 3 is the Chodosh report and supplement. Did you have that in your possession, or did somebody give that to you?

A. I don't quite understand your question. Can you be more specific?

Q. Who gave you the Chodosh report and supplement?

A. Oh, now I understand your question.

That was during the discussion of the topics. My attorney or attorneys mentioned the evaluation report by Dr. Chodosh; therefore, I asked my attorney or attorneys to arrange for the delivery of such report to me.

Q. Item 4 is the Bottorff report. Why did you read that?

A. Likewise, during the

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discussion, the attorneys not only mentioned the report by Dr. Chodosh, but also this report. I, therefore, wanted to find out what is in such a report. Therefore, I asked the attorneys to have that report delivered to me.

Q. Item 5 is the Wang report. Why did you read that?

A. The reason why I reviewed the Wang report was because during my communication with Min Li, spelled as M-I-N, last name L-I, he mentioned that Dr. Wang at the early stage did a preliminary investigation and generated a report.

I also wanted to find out the content of this report. Likewise, I asked my attorneys to have that report delivered to me.

Q. Were you told anything about a toxicologist named Janice Britt?

MR. BERNARDO: Object to the form of the question, and direct the witness not to answer to the extent that she was told anything by counsel.

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But otherwise you can answer.

MR. SLATER: Let me ask it differently. New question.

BY MR. SLATER:

Q. In your preparation, did you learn of the existence of a toxicologist named Janice Britt?

A. No, I didn't.

Q. During your preparation, were you made aware of someone named Dipak Panigrahy?

MR. BERNARDO: Object to the form of the question. Same objection.

Adam, you refer to last name with the rephraseology.

BY MR. SLATER:

Q. As part of your preparation, did you learn of the existence of a doctor named Dipak, D-I-P-A-K, Panigrahy, P-A-N-I-G-R-A-H-Y?

A. I don't know of this person.

Q. During your preparation, did you become aware of the existence of Dr. Stephen Lagana?

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A. Not for this person. I don't know of this person.

Q. During your preparation, did you become aware of the existence of Dr. Steven Hecht?

A. No, I never saw this name before.

Q. During your preparation, did you become aware of the existence of Dr. Etminan?

A. I don't believe I know this person.

As for all the people you just mentioned, since they all bear the English names, even had I seen those names in my review of the documents, I would have skipped those names; therefore, I would not have any recollection of those names. I don't know any of them.

Q. During your preparation, did you become aware of the existence of Dr. Madigan?

A. Seems like I don't have any impression.

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Q. As part of your preparation, did you read the transcripts of the depositions of Min Li, Peng Dong, Linda Lin, or Hai Wang?
A. Only excerpts. Only a very short excerpt. I didn't read much.
Q. Did you ever read your own deposition transcript?
A. Yes, I did.
Q. Did you take notes when you prepared for this deposition?
A. No, I didn't take any notes.
Q. Do you know what excerpts you looked at from the depositions of Min Li, Peng Dong, Linda Lin, and Hai Wang?
A. I don't recall, because the excerpt was quite short and didn't say much. And I took a quick look and didn't find any issue, so I do not recall what it said.
Q. Did you select the excerpts to review, or did somebody else select the excerpts for you?
A. Likewise, it was during the discussion on the topics, the attorneys

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mentioned those transcripts that might be relating to those topics, so I asked the attorneys to provide some excerpts for me to review.
However, since those excerpts are in English, and I don't read English, the workload to translate those excerpts was too high, so I only read a small portion of those excerpts, maybe a part of Peng Dong's deposition transcript, and I didn't find that very useful.
Instead, I found that oral communication with those people would be more helpful and would give me more information; therefore, I didn't read much of those excerpts.
Q. Did somebody translate the excerpts that you did read?
A. That is correct.
Q. Who?
A. For some of those, as I just stated in my prior testimony, I asked a person called Wei Cheng, W-E-I, last name C-H-E-N-G, from the QA department to help me.

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Q. Item 6 on this list is 1978 IARC monograph excerpts. Is that 1978 IARC monograph found in the files of ZHP?
A. I don't quite get your question. However, likewise, I received this document through my attorneys, and I also got help for the Chinese translation.
The original monograph was a thick book in English, so I only had the excerpt, the comment part, translated into Chinese for me to review.
Q. Item 8 is Gomm, G-O-M-M, et al. It's a medical article.
Did you read that?
A. Yes, I did.
Q. Why?
A. That was because this article also commented on the impact of NDMA in valsartan on health. That's why I asked them to provide this document to me for review.
Q. When you say it commented on the impact of NDMA on health, did that include the statistically significant finding of a causal relationship between the NDMA in

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the valsartan pills and liver cancer?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I did review the content, and also reviewed the conclusion.
As for the specifics, you had better just show it to me so that we can have a better discussion.
However, I do have some recollection, even though the recollection is not quite clear.
I did remember that in conclusion, the risk that NDMA caused to human health was not existing.
At the end of the article, it did mention and list certain issues and listed out some factors of uncertainty, but as the conclusion, the article did say that NDMA did not cause any risk to human health.
If you want to have a detailed discussion regarding the content, we'd better just take a look at this

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article.
BY MR. SLATER:
Q. That was your understanding of the conclusion of the article, what you just told me?
A. Well, that is correct.
Q. You're not a toxicologist, right?
A. That is correct. I am not.
MR. SLATER: All right. Chris, let's put up the FDA warning letter previously marked as Exhibit 213.
(Whereupon, Exhibit Number ZHP-213A and ZHP-213B were previously marked for identification.)
THE WITNESS: I see it.
BY MR. SLATER:
Q. Halfway down the first page is a paragraph that says -- rephrase. I'm going to start over.
The third paragraph of the FDA warning letter says -- rephrase. I'm going to ask it again.
The third paragraph states,

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"Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C., 351(a)(2)(B)."
Do you understand what "adulterated" means?
MR. BERNARDO: Object to the.
THE WITNESS: Dr. Shao, I quite understand -- I don't quite get the Chinese translation of this paragraph.
INTERPRETER SHAO: The interpreter would like to repeat the rendition.
MR. SLATER: Okay.
THE WITNESS: Maybe something is lost in the Chinese translation, so I still don't quite get the translation of this paragraph.
However, with this paragraph, I still have the recollection of FDA's conclusion, and I also understand what

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"adulterated" means.
BY MR. SLATER:
Q. What does "adulterated" mean?
A. In terms of the meaning of being adulterated with the aforementioned 501(a)(2)(B), there was a definition for the meaning.
Q. You said you understand what "adulterated" means. Tell me your understanding of the definition.
A. As for the understanding of the word "adulterated," I understand its meaning. It's actually a terminology only used by FDA. Typically we as enterprises do not use this term.
If you want an exact definition of this term, then you have to resort to Section 501(a)(2)(B).
But I understand what it means. That means that in our manufacturing process, our methods, facilities, and controls did not conform to the cGMP. That's what it means.
However, this term also has a time limit, and only FDA defines this term.

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I'm sorry, Dr. Shao. Maybe I didn't make myself very clear. What I said was, only FDA would use this term in their conclusion, and they also use such terms for their FDA approvals.
Q. You don't work in the regulatory department, do you?
A. That is correct, I do not work in the regulatory department. Instead, I work in the QA department.
Q. Who told you what "adulterated" means?
A. First of all, this term "adulterate" has something to do with GMP, and I would engage GMP in my daily work.
Secondly, for this term, I also consulted with Linda from the RA department and had a discussion with her about the meaning.
Q. And you under- -- rephrase.
And you understand that when the FDA made its finding of adulteration, its finding was based on violations of cGMP by ZHP in the manufacturing process for the

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valsartan, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I don't quite get your question. Can the interpreter repeat the rendition?
BY MR. SLATER:
Q. Sure.
A. I'm sorry. Something must have lost in the translation, so I don't quite get your question. However, I will do my best to respond to it.
As I stated in my prior statement, "adulteration" is a term that FDA would use. In their finding, they found there was some deviation there, that we actually did not conform to GMP.
Of course, it was within the scope of FDA's authority to make such a finding. However, from our company's point of view, we have always been conformed to GMP or in compliance with GMP. That position has been reflected in our response to FDA's warning letter, as well as the communications

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with FDA over a long period of time.
I'm not sure whether your question is answered.
Q. So you're telling me ZHP has never taken responsibility for its violations of cGMP?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I don't know whether it's because I'm from a different profession, I couldn't understand your question. After all, I'm not a lawyer. However, I will do my best to answer your question as follows.
First, after their discovery, FDA did gave us the warning letter stating that ZHP failed to conform to cGMP. However, from the company's point of view, we have been in compliance with the cGMP, which was also reflected in our response to the warning letter.
Even though the company has

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been in compliance with the cGMP, in order to work with FDA and the response to this finding, we did a lot of work for improvement seriously and diligently.
Secondly, our company is a responsible company. Ever since we received this warning letter, we stopped the sales in the US.
I don't know whether I got the key point of your question and answered your question, but I will try my best to answer this question.
BY MR. SLATER:
Q. In the FDA warning letter, the FDA says on the first page, "During our inspection, our investigators observed specific deviations including, but not limited to, the following.
"Number 1. Failure of your quality unit to ensure that quality-related complaints are investigated and resolved."
Later in the letter, "Number 2. Failure to evaluate the potential effect that

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changes in the manufacturing process may have on the quality of your API."
You're aware that the FDA found both of those deviations and put them in the warning letter, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I believe it should be put in this way. In the warning letter, FDA did put two deviations that they thought were deviations in the letter.
First, the investigation of -- on the complaints were not sufficient.
Secondly, the deviation regarding the evaluation of the potential effect from the changes.
Indeed, they put those two deviations in the warning letter.
BY MR. SLATER:
Q. The FDA also rejected ZHP's explanation and argument that it had not committed these deviations, correct?
MR. BERNARDO: Object to the

form of the question.
THE WITNESS: I wonder where I can find such statement that you just made or referred to in this warning letter. I failed to find such statements in the letter.
BY MR. SLATER:
Q. Let's go to page 4. The third paragraph under -- I'm sorry.
On page 4, the third paragraph under number 2 says, "Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that your process development study was adequate. We disagree. We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce."
Does that refresh you on what the FDA said in rejecting ZHP's response to the findings of deviations?
MR. BERNARDO: Object to the

form of the question.
THE WITNESS: Now I see this paragraph.
Indeed, FDA wrote this paragraph regarding the response we filed for the inspection.
And with regards to the evaluation of the investigation, FDA did write -- did write such a paragraph when we tried to respond to the finding of that deviation, the second one.
BY MR. SLATER:
Q. Let's go to page 2.
In the second-to-last paragraph, the FDA stated to ZHP, "Your response states that NDMA was difficult to detect. However, if you had investigated further, you may have found indicators in your residual solvent chromatograms alerting you to the presence of NDMA. For example, you told our investigators you were aware of a peak that eluted after the toluene peak in valsartan API residual solvent chromatograms

where the presence of NDMA was suspected to elute. At the time of testing, you considered this unidentified peak to be noise and investigated no further. Additionally, residual solvent chromatograms for valsartan API validation batches manufactured using your zinc chloride process, with DMF in 2012 (C5355-12-001, C5355-12-002, and C5355-12-003) show at least one unidentified peak eluting after the toluene peak in the area where the presence of NDMA was suspected to elute."
Does that refresh your memory that the FDA also disagreed with ZHP's explanation regarding the difficulty in detecting NDMA?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I disagree with this paragraph. My disagreement was also reflected in our response to what was written by FDA in this paragraph.
That was because, retrospectively, nobody at that time

was aware of the existence of NDMA in valsartan. Now, of course, everything is very clear. But, retrospectively, had we known the existence of the NDMA, we would have found that was also in our response to FDA.
I also listed FDA's statement in the list of documents, and I also believed that typically if we are aware of one impurity, we would develop the analytical method accompanying.
At that time with regard to NDMA, nobody was aware of that, so we developed the analytical method according to the common industry practice as well as the FDA's requirement.
But at that time nobody knew what NDMA was. So, as I said, had we known the method, the impurity, we would have developed the method accordingly. Since we didn't have the method, we were not aware of such an

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impurity in the existence.
BY MR. SLATER:
Q. Looking now at the last full paragraph on page 2 of the warning letter, the FDA states, "Your response also states that you were not the only firm to identify NDMA in valsartan API. In your case, FDA analyses of samples identified amounts of NDMA in valsartan API manufactured at your firm that were significantly higher than the NDMA levels in valsartan API manufactured by other firms. FDA has grave concerns about the potential presence of mutagenic impurities in all intermediates and API manufactured at your facility, both because of the data indicating the presence of impurities in API manufactured by multiple processes, and because of the significant inadequacies in your investigation."
Does that refresh your memory that the FDA also disagreed with ZHP's explanations? Does that help you to remember that?
MR. BERNARDO: Object to the

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form of the question.
THE WITNESS: I found discrepancy between the translation given by the interpreter just now and the Chinese version of the warning letter. I don't know what caused the discrepancy in translation.
However, based on the Chinese translation provided by my colleagues for this FDA warning letter, after their investigation, FDA did provide such a view based on their awareness of NDMA; therefore, their conclusion was a respective conclusion, because at that time everyone would know the existence of NDMA.
That was the base where FDA thought our investigation was not sufficient. However, back at that time nobody was aware of NDMA.
In our response to FDA, we stated that ZHP was not the only firm that identified NDMA. That was because we reviewed the public

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announcement made by FDA and was made aware of that. Such a position was also reflected in our response to FDA. We were very clear about the whole process.
BY MR. SLATER:
Q. The findings by the FDA constituted violations of cGMP and thus met the definition of "adulteration" as you understand the definition of "adulteration," correct?
MR. BERNARDO: Object to the form of the question.
BY MR. SLATER:
Q. I'll ask it differently. Let me withdraw the question and start over.
The deviations found by the FDA met the definition for "adulteration," correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I don't quite get your question. I am sorry, I don't know what you're asking about.

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BY MR. SLATER:
Q. The deviations discussed by the FDA in their warning letter constituted adulteration of the valsartan, correct?
MR. BERNARDO: Object to the form of the question.
BY MR. SLATER:
Q. Let me ask the question again. Let me withdraw it and ask it again.
Based on the deviations from cGMP found by the FDA, the valsartan was adulterated, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: Maybe I already spoke in my prior statement, the term "adultration" -- "adulteration," rather, is a term that FDA would use. That's okay. That's within the scope of their authority.
Due to what they thought was a deviation from the cGMP, FDA issued in their warning letter in November 2018 that that was adulteration. However,

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that doesn't mean that valsartan itself was adulterated.

MR. BERNARDO: Adam, I've been trying to let you finish this line, but we've been going for almost an hour and a half, if there's a good time to take a break.

MR. SLATER: I'd like to go another five minutes or so and just try to finish this question off.

MR. BERNARDO: Sure. I've been trying not to interrupt, but we've been going an hour and a half, and I just want to make sure --

MR. SLATER: I'm fine going as long. I mean, if the witness doesn't need a break and I don't need a break, I don't know that we need to stop.

But let me go for a couple more minutes, and if you want to have a break, I can't stop you. That's why I load up the food on my desk.

MR. BERNARDO: I need the opposite of that.

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BY MR. SLATER:

Q. Based on your understanding of the definition of "adulteration," because of the deviations from cGMP found by the FDA, the valsartan manufactured with the zinc chloride process was adulterated, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That is not correct. I totally disagree. It was in November 2018 that FDA issued this warning letter.

However, before November 2018, ZHP already terminated the manufacturing of valsartan using zinc chloride process in June of 2018.

Therefore, I do not agree with the statement that the products made by ZHP was adulterated, according to FDA's warning letter.

BY MR. SLATER:

Q. You understand the FDA was talking about the valsartan API manufactured with the zinc chloride process, correct?

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A. I don't get the translation. Could the interpreter repeat the rendition?

I wonder what time frame are you referring to, or what specific time point are you referring to?

In terms of the time frame in my response to you, actually, when we found out the existence of NDMA in valsartan in June 2018, we terminated the manufacturing. Prior to that time, we did manufacture valsartan using zinc chloride process.

MR. SLATER: If you want to take a break, we can take a break now.

MR. BERNARDO: Thank you, Adam. Appreciate it.

THE VIDEOGRAPHER: The time right now is 8:35 a.m. We're off the record.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: The time right now is 8:49 a.m. We're back on the record.

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BY MR. SLATER:

Q. During your preparation for this deposition, did you become aware of the existence of David Chesney?

A. No.

Q. Are you aware that there's a person named David Chesney that was hired to be the cGMP expert witness on behalf of ZHP in this litigation?

A. I'm not aware of that.

Q. Were you aware that Mr. Chesney, when he had his deposition taken, testified that ZHP violated cGMP in its risk assessment in connection with the manufacturing process for the zinc chloride manufacturing process?

MR. BERNARDO: Object to the form of the question.

BY MR. SLATER:

Q. Let me reask the question. I think I double-spoke at the end, so I think it needs to be asked again.

During your preparation for this deposition, did you become aware that

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David Chesney, ZHP's cGMP expert, testified that ZHP violated cGMP in connection with the manufacture and manufacturing process for the valsartan manufactured with the zinc chloride process?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I'm not aware of that.

BY MR. SLATER:

Q. You were given certain expert reports as part of your preparation for this deposition. Wouldn't you have liked to have seen the expert deposition of the cGMP expert for ZHP?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I did review some of the expert reports, especially the health risks. As I told you before, I read the report by Dr. Chodosh and I communicated with him.

So my first point is on the topic of adulteration, that is related

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to GMP. As the person in charge of QA, I engage in GMP activities, so I don't know what you mean.

As for FDA's warning letter, requests, or questions, we always try to respond seriously by organizing human resources for such responses. So I don't know what you mean.

BY MR. SLATER:

Q. You were given the reports of certain defense experts. Would you have liked to have seen Mr. Chesney's deposition, since he was ZHP's expert on GMP and testified that ZHP violated cGMP in the zinc chloride manufacturing process?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: When I was trying to get familiar with the topics, I was not made aware of that. That is why I did not have any communication with him or had the chance to review his report. That's number one.

Number two, our company's

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position in our response is that we never violated any cGMP requirements. We were always in compliance with cGMP.

BY MR. SLATER:

Q. Earlier you said that ZHP did a lot of work to improve its processes. The reason that ZHP had to improve its processes is because they violated cGMP, right?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: In response to your question, our company has been in compliance with cGMP from beginning to end.

In order to work with FDA, in our response to FDA we made it very clear that we have been in compliance with cGMP.

However, in order to work with them, we did a lot of work in a proactive and responsible way to make some improvements and enhancements.

It has always been our

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company's position that we've been in compliance with cGMP. The reason we did a lot of work for improvement and enhancement was to work with FDA, not because we violated cGMP.

So we have always been very clear in our response to reflect the company's position. That is also eventually recognized by FDA in their approval.

BY MR. SLATER:

Q. You said that your company was always proactive and responsible in the steps it took, but let's look at page 4 of the warning letter again and address what the FDA had to say about that.

Let's look at the second-to-last paragraph. The second-to-last paragraph says, "Your response does not describe sufficient corrective actions to ensure that your firm has adequate change management procedures in place: (1) to thoroughly evaluate your API manufacturing process, including changes to those

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processes; and (2) to detect any unsafe impurities, including potentially mutagenic impurities. For FDA's current thinking on control of potentially mutagenic impurities, see FDA's guidance document M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk for approaches that FDA considers appropriate for evaluating mutagenic impurities, at," and then there's a link there.

So, in fact, does that refresh your memory that the FDA was not satisfied with ZHP's proposed corrective actions and forced ZHP to do more?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: Indeed, in this warning letter FDA made such writings in response to our prior response and made such requests. Indeed, it was written here. However, it doesn't mean that we violated GMP. I do not agree with such interpretation.

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FDA, over here, indeed wrote down what they thought would be a better corrective action as a regulatory authority.

(Zoom technical issue.)

MR. SLATER: I'm back. I guess I disappeared for a second, and I think I lost --

MR. BERNARDO: You disappeared again, in an interesting pose.

THE VIDEOGRAPHER: Should I go off the record?

MR. BERNARDO: Sure.

THE VIDEOGRAPHER: The time right now is 9:06 a.m. We're off the record.

(Off the record for technical issue.)

THE VIDEOGRAPHER: The time right now is 9:09 a.m. We're back on the record.

MR. SLATER: Okay. Let's go to page 6, Chris. Great.

///

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BY MR. SLATER:

Q. Looking at the first full sentence om -- rephrase.

Looking at the first full paragraph, which is only a sentence, on page 6 of the FDA warning letter, the FDA informs ZHP, "FDA placed your firm on Import Alert 66-40 on September 28, 2018."

And you understand that ZHP was placed on Import Alert because of the cGMP violations found in connection with the zinc chloride manufacturing process, right?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: Judging from the content of this letter, I do not see any causal effect relationship between the two. I'm aware that FDA did put us on such an Import Alert.

MR. SLATER: Hello? Can you guys hear me?

MR. BERNARDO: Yes. You did seem to freeze for a minute, but...

MR. SLATER: So where are we?

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I think you were reading the question to the witness, Dr. Shao?

MR. BERNARDO: No, I thought she answered and you had her answer.

MR. SLATER: You know what, I didn't hear the answer. Can I have the answer read to me, please? I must have missed it when I was stage left again.

(Whereupon, the reporter read back the answer:

"ANSWER: Judging from the content of this letter, I do not see any causal effect relationship between the two. I'm aware that FDA did put us on such an Import Alert.")

BY MR. SLATER:

Q. The next paragraph says -- rephrase.

The next paragraph of the warning letter states, "Until you correct all deviations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or

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supplements listing your firm as a drug manufacturer."

So you understood that FDA was taking this action because of the deviations from cGMP, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That interpretation is incorrect. I disagree with such a view.

In FDA's warning letter, they did state such procedure that until the corrections were completely made, all the applications submitted by our company, as well as the supplements, will be upheld. That's their procedure.

We're aware of that, but that doesn't mean that we violated the cGMP.

BY MR. SLATER:

Q. The corrections that the FDA was referring to were corrections of the cGMP violations listed in this letter, correct?

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MR. BERNARDO: Object to the form of the question.

INTERPRETER SHAO: The interpreter was asked to repeat the rendition.

THE WITNESS: The corrections that FDA was referring to were the corrections for the deviations from the cGMP listed in this warning letter, as we discussed before.

BY MR. SLATER:

Q. And, therefore, you agree that ZHP had violated cGMP and needed to correct those violations, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That is incorrect. Why we took some actions for improvement was to work with FDA. That was very clear with FDA in our response letter. That has always been our position, that we did not violate any cGMP.

///

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BY MR. SLATER:

Q. Am I correct that no matter what evidence the jury hears at the trial of this case, your answer on behalf of ZHP will be that ZHP did nothing in violation of cGMP and acted appropriately in all things?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I don't understand what you're referring to by evidence of violation of cGMP that the jury would hear in the trial of this case.

I did mention in my prior statement that in our response to this warning letter, we made it very clear that it has always been the position of our company that we're being in compliance with cGMP.

That was so in our response letter. That was also the same in our communication with FDA afterwards. We have always been making that very clear.

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BY MR. SLATER:

Q. It will always be ZHP's position that it did nothing wrong and never violated cGMP in the manufacture of valsartan, no matter what evidence is shown, no matter what documents are seen, and no matter what testimony is provided by witnesses, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I disagree with -- I disagree with your statement. That is incorrect.

Our manufacturing of valsartan in ZHP could trace as back as in 2011 or maybe 2010. During the whole period of time, we have conducted a series of work before we started to manufacture valsartan in compliance with GMP.

We met the requirement of FDA. We did not start in the manufacturing of valsartan until the regulatory procedure and approval was complete.

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During the process, FDA conducted many inspections and came up with the conclusion that we were in the -- in compliance with GMP, except for this inspection. That was because the inspection was made after the discovery of NDMA. Therefore, they issued this warning letter.

In this warning letter, they listed those findings which our company made a response. Based on the above points, actually in addition to that, we were audited many times by EU, by Japanese, and Korean official authorities, and their conclusion was always that we were in compliance with cGMP.

So it's not like no matter what evidence was produced, that our company's position would be the same, that we were in compliance with cGMP. That's why I disagree with your statement.

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BY MR. SLATER:

Q. As you just said, once the FDA found out about the NDMA in the valsartan, it investigated, it found cGMP violations, it issued a warning letter, and it put ZHP on the Import Alert, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I don't see any causal effect relationship between the two. The warning letter issued by FDA made it very clear the reason why they issued such a letter was because they believed that we failed to meet their requirement by two deviations, and that is not because we violated cGMP simply by manufacturing valsartan.

We have already discussed about that, and I've already stated in my prior statement that when we were manufacturing valsartan in June 2018, we found NDMA and we reported that discovery to FDA. Afterwards, FDA organized this inspection.

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I was just wondering why you would come up with such a conclusion. You know, as discussed before, after we made response to FDA, FDA eventually gave the approval by issuing this IEA report. Actually, EIA report.

Actually, in 2012, we already received this EIA report from FDA.

Do you mean that we have been violating the cGMP all the time? What do you mean by saying that?

BY MR. SLATER:

Q. It was never acceptable for there to be NDMA in the valsartan that ZHP was selling, correct?

A. I don't quite understand your question. As I said in my prior statement, the reason why we were selling valsartan in the US and we were manufacturing valsartan was because of the approval by the FDA. We met their requirement.

Q. It's your testimony that the FDA approved the sale of valsartan containing

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NDMA?

A. That is not my testimony. I think you misunderstood me.

Before June 2018, we didn't know about NDMA, and I believe FDA was not aware of NDMA. That's why we were given the approval to manufacture valsartan.

However, in June 2018, after we discovered NDMA, we conducted investigations, suspended manufacturing, and took corresponding actions.

Q. The FDA would never have approved the sale of ZHP's valsartan if it knew that there was NDMA in it.

You agree with that, right?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: First, I don't think your hypothesis is legitimate. That is because when we were applying for approval for manufacturing ND- -- manufacturing valsartan, we were not aware of NDMA. Neither were they.

Even if your hypothesis were

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legitimate, FDA would have asked our company to take actions in quality control to limit the content of NDMA had they been aware of the existence of NDMA, and would have asked us to take corresponding actions.

In other words, I believe our company would have done our best to meet the requirement of FDA.

BY MR. SLATER:

Q. One of the requirements the FDA expected ZHP to meet would have been compliance with ICH M7 at all times that ZHP sold the valsartan, correct?

A. I'm not sure of the scope of sale that you're referring to.

Q. At all times, the FDA expected ZHP to comply with ICH M7 in its assessment and control of DNA-reactive mutagenic impurities, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I don't quite understand your question, but I'll

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give it a try.

First point I would like to make is that ZHP as a drug manufacturer has been expected by FDA to meet the requirement of M7.

My second point is, our company has always been in compliance with M7.

BY MR. SLATER:

Q. So you think that ZHP was in compliance with ICH M7 when it was selling valsartan that contained the mutagenic/genotoxic impurity NDMA in the United States?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I don't agree with your statement because I think the causal effect relationship should be the opposite; therefore, I believe that your statement is completely incorrect.

Our company has always been in compliance with ICH M7 in controlling impurities. However, we were not

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aware of NDMA until June 2018, nor was FDA. Therefore, for something you don't know, you really cannot do anything about it.

Prior to that, because of the unawareness of NDMA, you cannot accuse us of violating ICH M7. Actually, our company has always been in compliance with ICH M7.

Therefore, I do not agree with your statement that our company was selling NDMA containing valsartan knowingly, or on purpose, or deliberately.

I would like to also add something else. My first point is that we were expected to be in compliance with ICH M7 when we were going through the regulatory process. Otherwise, FDA would not have approved our application.

It was FDA's observation that we were in compliance with ICH M7, and they also confirmed so through

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multiple inspections. Otherwise, they wouldn't have brought it up in their previous inspections.

My second point is, had we known the existence of NDMA prior to 2018, why did we delay the recall and other work until then? What was the reason we would do that?

BY MR. SLATER:

Q. There would never be an acceptable reason to do that, right?

A. To do what? Are you referring to the sales of valsartan?

Q. I'll ask the question differently.

You just said if you had known of the presence of NDMA, why did you delay the recall until 2018.

My question to you is, you agree that it never would have been acceptable under any circumstances to delay disclosure to the FDA and to your customers once you found out that there was NDMA in the valsartan, correct?

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A. With regard to your hypothetical question, I have to say that indeed in June 2018, once we found out about the existence of NDMA, we disclosed to FDA right away, and we did our best to develop analytical methods.

Q. Can you answer my question, please?

A. I think I already gave you a direct answer.

Had we known the existence of NDMA prior to June 2018, we would have done the same as we did in June 2018, which was that we made an immediate disclosure to the FDA, and we immediately started communication with FDA and did our best to develop analytical methods.

Q. You were required to take the steps that you took in 2018 as soon as you knew that there was NDMA in the valsartan, correct?

A. We took also many actions at that time, such as suspension of the manufacturing and suspension of the sales and

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locking up all the manufactured goods in the warehouse. Those actions were taken spontaneously. Nobody required us to do so.

Q. ZHP needed to take those steps as soon as ZHP became aware that there was NDMA in its valsartan, correct?

A. That was the decision we made after the company conducted the deviation investigation.

Q. My question that I'm asking you to answer with a simple yes or no, please, as soon as ZHP knew that there was NDMA in its valsartan, it was required to disclose this to the FDA and to its customers and to stop selling the valsartan with the NDMA in it, correct?

MR. BERNARDO: Object to the form of the question.

BY MR. SLATER:

Q. Let me rephrase the question. Let me withdraw it and ask it differently.

The steps that ZHP took in June 2018, you would agree with me ZHP would have needed to take the same steps if it had

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learned that there was NDMA in the valsartan at an earlier time, correct?

A. That is correct.

Q. In fact, as of at least July 27, 2017, you and others in your company knew that when valsartan was quenched with sodium nitrite, it was forming NDMA, correct?

A. That is incorrect.

MR. BERNARDO: Adam, we've been going over an hour. If you're going to turn to that topic and we could take a break, that would be good.

MR. SLATER: Sure. Sure.

MR. BERNARDO: Thank you.

MR. SLATER: Go off the record.

THE VIDEOGRAPHER: The time right now is 9:52 a.m. We're off the record.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: The time right now is 10:08 a.m. We're back on the record.

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BY MR. SLATER:

Q. A few moments ago you asked the question why would ZHP not have disclosed the presence of the NDMA in its valsartan as soon as it knew.

And I guess in response to you asking that question, I would pose the possibility that ZHP was making so much money, and in the words of Jun Du to the FDA investigator, "dominating the world market for valsartan," that that was the incentive that unfortunately ZHP was swayed by and didn't take action to stop selling the NDMA-contaminated valsartan earlier.

That's certainly something that could have happened here, right?

A. This is incorrect. This is completely incorrect. I'm not aware of the statement made by Jun Du. However, I don't believe your statement is correct.

Q. If ZHP failed to disclose the presence of the NDMA earlier because ZHP wanted to continue to profit from that valsartan, that would have been completely

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improper, correct?
A. I found your statement sounds incredible. ZHP is a manufacturer of valsartan.
I don't quite understand your statement, actually. Could Dr. Shao repeat a rendition?
Well, if the company wants to make more profits, then it could have taken better approaches, such as removal of the impurities. By doing that, the company could have made more profits.
Q. ZHP only disclosed the presence of the NDMA in the valsartan after Novartis forced ZHP to do so, right?
A. That is incorrect.
Q. Have you read the e-mails between ZHP and Novartis that led to the disclosure of the NDMA in the valsartan?
A. While I was organizing the deviation investigation, I already read that e-mail.
In that e-mail, Novartis was only stating that they were suspecting that

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the impurity might be NDMA.
Q. And then ZHP confirmed it was NDMA, and ZHP was not moving quickly enough, and Novartis had to threaten ZHP to force ZHP to disclose the NDMA, correct?
A. I don't know where you came up with that narrative. That's not what I'm aware of.
Q. Let's go back to the July 27, 2017 e-mail that Jinsheng Lin sent to you and copied several people.
You have that e-mail in your binder, right?
A. That is correct.
Q. It's item number 11 in your binder, correct?
A. Let me check. That is correct. Item number 11 is that e-mail, while item number 12 is the attachment to that e-mail.
Q. Jinsheng Lin is a Ph.D. organic chemist, correct?
A. Since we worked in different departments, I was never familiar with his qualifications, so I don't know about that.

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All I know is that he works in CEMAT, and he is someone that would conduct analysis on impurities.
Q. He was in charge of the lab for process and degradation impurity research at CEMAT, correct?
A. He was not the person in charge. I believe Min Li is actually the person in charge.
Q. Min Li was in charge of all of CEMAT. Jinsheng Lin was in charge of the lab for process and degradation impurity research, correct?
A. Are you referring to now or back in 2017?
Q. 2017.
A. If you're referring to the time in 2017, if my memory serves me right, he was just a regular analytical personnel at CEMAT. Because recently I noticed there was some promotions, if my memory serves me right.
MR. SLATER: Chris, let's put up Exhibit 431, please.
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(Whereupon, Exhibit Number ZHP-431 was previously marked for identification.)
BY MR. SLATER:
Q. Actually, you know what, you can actually give -- Exhibit 431 is the version in Chinese and Exhibit 432 is the English translation of the PowerPoint. Let's work with 432 on the screen, but you can certainly -- I'd like to give the witness 431 so she can see that as well.
(Whereupon, Exhibit Number ZHP-432 was previously marked for identification.)
BY MR. SLATER:
Q. Let's go to the third page.
This is a PowerPoint that we've been provided that my understanding is dated November 2017 regarding CEMAT.
Do you see that?
A. I don't know. I've never seen this document before.
Q. So in your work that you did to prepare for this deposition, you didn't see

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this PowerPoint, which has been used in other depositions, in order to give you background about Jinsheng Lin's role at the company in 2017, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That's not correct. As I said before, in order to prepare for this deposition, I worked very hard to get familiar with the topics with regard to the three topics that I have to speak on. I did a lot of work in preparation.

But this document was certainly not on the list of the documents that I needed to review. Had you told me that I had to review this document, I would have reviewed this document.

Anyway, with that, I have to say even though I already reviewed a lot of documents, that doesn't mean that I reviewed all the documents.

BY MR. SLATER:

Q. Looking now at the third page

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of this PowerPoint, you can see that it is titled that it's -- rephrase.

Looking now at the third page of this PowerPoint, it refers to the lab or laboratory for process and degradation impurity research and says that the responsible person for that laboratory was Jinsheng Lin, correct?

MR. BERNARDO: Objection to the form of the question.

THE WITNESS: As I mentioned earlier, my English is poor. If possible, could someone translate this page for me since I do not understand what it says in English here?

MR. SLATER: The version in Chinese or Mandarin is Exhibit 431.

Chris, if you could put that up.

THE WITNESS: Can you show me the cover of this document so that I can figure out who prepared this document?

MR. SLATER: You can do that,

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Chris. You can show her the cover.

THE WITNESS: Can you scroll down to second page?

Now I see. It was Wen Quan Zhu that prepared this document. Wen Quan Zhu's named is spelled W-E-N, Q-U-A-N, last name Z-H-U. But the document didn't say when it was prepared.

BY MR. SLATER:

Q. I'm representing to you that the information we have says November 2017.

A. Is that so?

Oh, now I know that since CEMAT is located at the corporate headquarters in the Xunqiao site of Linhai County, Xunqiao spelled as X-U-N-Q-I-A-O, while I work at the Chuannan site, also in Linhai County, in the Chemical Engineering Industrial Park. So we're looking at different sites and different departments.

I was never familiar with the title and job description of Jinsheng Lin, and I didn't make any effort to gather information regarding that during my

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preparation.

In the past, I did not get to interact with CEMAT. Only once there was an issue and we needed their support to resolve the issues, we would approach.

MR. SLATER: Let's go back to the third page.

BY MR. SLATER:

Q. This page -- rephrase.

The third page of this PowerPoint shows that Jinsheng Lin was the responsible person in this laboratory for process and degradation impurity research, correct? That's what it says on the page, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That's what it says on this page.

BY MR. SLATER:

Q. Looking now at the e-mail of July 27, 2017, that Jinsheng Lin addressed to you. Do you see that in front of you?

MR. SLATER: You can take this

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document down, Chris.
THE WITNESS: I see it.
MR. SLATER: And we'll put up on the screen 296, which is the English version, but the witness can refer to the Exhibit 295, which is the original Mandarin.
That's not the exhibit.
(Whereupon, Exhibit Numbers ZHP-295 and ZHP-296 were previously marked for identification.)
BY MR. SLATER:
Q. This e-mail was written to you and copied to multiple people, correct?
A. That is correct.
Q. Let's look at the second page.
At the top, one of the things that Jinsheng Lin wrote in this e-mail is that nitrosodimethylamine occurs in valsartan when it's quenched with sodium nitrite.
And, in fact, you can confirm to me that's a true statement; that was the root cause for the NDMA in the zinc chloride process valsartan, correct?

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MR. BERNARDO: Object to the form of the question.
THE WITNESS: That is incorrect. Actually, your interpretation did not reflect the intent of this sentence.
I have to admit that this e-mail is poorly written and ambiguous, to be the least. However, your interpretation is oversimplified. You could not just take this sentence out of the context and come up with this interpretation, which did not reflect the true intention of Dr. Lin, which was confirmed through my communication with him.
BY MR. SLATER:
Q. You realize you've already testified under oath in your prior deposition that the e-mail says in part that there was nitrosodimethylamine in valsartan and that it occurred when the valsartan was quenched with sodium nitrite.
You know you testified to that

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under oath already, right?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I don't quite get your question. Indeed, I recall this e-mail was asked about in my prior deposition. However, you can resort to the relevant evidence for my response.
BY MR. SLATER:
Q. It's a true statement that in July 2017 there was NDMA in the valsartan that your company was manufacturing, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I don't know how to respond to this question.
Well, let me put it in this way. I believe the right way to put it is that not until June 2018 did we become aware of the existence of NDMA in valsartan that we manufactured prior to that date.
///

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BY MR. SLATER:
Q. Please answer my question with a yes or a no.
In July of 2017, there was NDMA in the valsartan manufactured by ZHP with the zinc chloride process, correct?
A. A point of clarification. A point of clarification. Are you asking whether we were already aware that there was NDMA in the valsartan we manufactured with the zinc chloride process in July 2017?
Is that what your question is about?
Q. No. My question is, there was NDMA in the valsartan manufactured by ZHP with the zinc chloride process in July 2017, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I don't know whether it is because of the difference between English and Chinese, I am still puzzled by your question. I will do my best to

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respond to your question.
Not until June 2018 did we become aware that there was NDMA in the valsartan that we manufactured in 2017 using the zinc chloride process.
Prior to June 2018, we were not aware of the existence of NDMA that we manufactured using the zinc chloride process; the existence of the NDMA in the valsartan that we manufactured using the zinc chloride process, that is.
BY MR. SLATER:
Q. I have tables -- rephrase.
I have tables of NDMA test results from testing of batches going back to the first validation batches that were manufactured in 2011 and then in 2014 and forward. Every single one of those batches of valsartan manufactured with the zinc chloride process contained NDMA, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That is correct.

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However, that was the result of retrospective testing of all those batches after we learned about the existence of NDMA in valsartan in June 2018.
BY MR. SLATER:
Q. When Jinsheng Lin said in his July 27, 2017 e-mail that there was NDMA that occurs in valsartan when quenched with sodium nitrite, that was an accurate statement, correct?
A. That's incorrect. I don't think your interpretation was a correct reflection of the intention of the author.
Q. That's what the words on the page say, correct?
A. That's incorrect. That -- as I stated in my prior testimony, this e-mail was poorly written and complicated, as you could see here, even though that was the words that said so on this page. But the whole e-mail is about the impurity found in the technical improvement for irbesartan.
I communicated with Peng Dong

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and Jinsheng Lin and eventually figured out, after reading this e-mail again and again, that this e-mail was trying to make a comparison with NDMA when it was talking about the toxicology of this impurity from being the technical improvement of irbesartan.
Q. And in making the comparison to the NDMA in valsartan, Dr. Lin also pointed out that the NDMA was forming when it was -- when the valsartan was quenched with sodium nitrite during the manufacturing process, correct? That's what the words on the page say.
A. That's incorrect. In order to correctly interpret this e-mail, you have not only to read through this e-mail, but also the attachment.
In order to truthfully understand the meaning of this e-mail, I did a large amount of work, including communicating with Jinsheng Lin himself. Until then I fully understood the intention of this e-mail by reading the e-mail from top

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to bottom.
Q. The statement that the NDMA occurred in valsartan when it was quenched with sodium nitrite, that's a true statement, and that's actually the root cause for the NDMA in valsartan, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's incorrect. That's incorrect. That's completely incorrect.
As I mentioned before, Dr. Jinsheng Lin at that time was only someone that would conduct analysis of impurities at CEMAT.
Through communication with him, I learned at that time he had very limited knowledge of the process of manufacturing valsartan. That limitation was only to the attached patent, from which he would try to come up with this comparison of Impurity K, nitroso compound, and NDMA.

According to him, NDMA was a quite common impurity. That's why he wanted to use NDMA to have a comparison with the impurity he found in the technical improvement of irbesartan.

Through communication with Jinsheng Lin, he actually was not aware of the NDMA in valsartan at all at that time.

BY MR. SLATER:

Q. Let's go further down in the e-mail to the second-to-last paragraph.

He says, "This is a common problem in the production and synthesis of sartan APIs. It is recommended to improve other quenching processes (such as NaClO) along with the optimization of the valsartan sodium azide quenching process."

And I want to focus on the last part. Do you see where it says that he was recommending "the optimization of the valsartan sodium azide quenching process"?

A. I see that paragraph. I see

the paragraph you just referred to.

Q. Are you aware that in the deviation investigation report DC-18003, there's a section that refers to valsartan zinc chloride process optimization, and that optimization which Dr. Lin had recommended in 2017 is exactly what your company did to try to remove the NDMA from the valsartan?

Are you aware of that?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I believe you completely misunderstood what's written here, as well as what's written in DC-18003. I believe you have a complete misunderstanding regarding the two documents.

BY MR. SLATER:

Q. You know that NDMA is different from Impurity K as that term is used in the patent, right? Right?

A. Indeed, those two impurities are different. They are both nitroso compounds.

Q. So it's your testimony that Jinsheng Lin accidentally correctly guessed that there was NDMA in valsartan in July of 2017? That's your explanation?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I completely disagree with you.

BY MR. SLATER:

Q. So it's your testimony that when Jinsheng Lin said there was NDMA in valsartan, he really meant to say there's an unknown nitrosamine in valsartan?

Do I understand you correctly?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I don't understand your question. Can the interpreter repeat the rendition?

I don't agree with you. It is incorrect. As I said before, Jinsheng Lin was at that time only someone who would conduct analysis in CEMAT, as shown in the PowerPoint file. He was

actually doing the impurity analysis or impurity degradation analysis and the structure confirmation.

CEMAT is located at the company headquarters in Xunqiao, while valsartan at that time was manufactured at the Chuannan site.

I already communicated with Jinsheng Lin. At that time we were working in different sites, so his understanding regarding the impurity in valsartan was only limited to Impurity K mentioned in that happened.

He at that time was not aware of the existence of NDMA in valsartan. That was because of the limitation of the analytical method.

A good analytical method is capable of testing out the targeting impurities. At that time, the analytical method failed to detect that impurity, so Jinsheng Lin or we did not have any awareness of the NDMA in valsartan at that time.

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BY MR. SLATER:
Q. So it's your testimony that Jinsheng Lin didn't know there was NDMA in valsartan, yet in his e-mail he said there was NDMA in valsartan.
MR. BERNARDO: Object to the form of the question.
BY MR. SLATER:
Q. Do I understand what you're saying?
A. That is why I was confused when I was reading his e-mail in the first place, the same confusion you are having right now.
Needless to say, this e-mail was poorly written, and it was hard to understand.
Even when it was written in Chinese, I could not get what is said until I communicated with the author himself and read through not only the body of the e-mail, but also the attachment. Not until then did I figure out what it was saying.
So it is understandable that when it is translated into English, you're

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having a hard time understanding the content. Even when it was written in Chinese, I had the same problem, too.
Q. Well, you actually aren't having trouble reading the e-mail, because we agree it says that there is NDMA in valsartan. We've already agreed on that, right? That's what the e-mail says, the words on the page. You've already told me that, right?
A. Even though that sentence in the e-mail says so, you would not get the correct understanding until you look into the context.
I failed to get what the e-mail said in the beginning until I had communication with the author, Jinsheng Lin. He told me at the time he was -- of the existence of NDMA in valsartan.
He also -- I also told you at that time that was because there was no capable analytical method that would test out such impurity; therefore, nobody could test and confirm the existence of NDMA in

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valsartan.
In addition, he was not a technician of valsartan. He was not in charge of this product. His understanding regarding valsartan was only limited to the Impurity K mentioned in the attached patent, not NDMA.
So if you look into the context of this e-mail, you can tell that at that time he was trying to make a comparison between NDMA and Impurity K and the impurity found in the technical improvement of irbesartan, since they were all nitroso compounds, and he was merely trying to make a toxicology comparison.
Q. And to be very clear, the words on the page not only say that there was NDMA in valsartan; they also say that the NDMA occurred in the valsartan when it was quenched with sodium nitrite.
Those words were accurate and true at the time the e-mail was written, correct?
A. That's incorrect.

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Q. Okay. Tell me what's incorrect. In July 2017, you've already agreed there was NDMA in valsartan, right? So that's correct?
Let me ask it again.
MR. SLATER: Dr. Shao, let me ask it again.
Q. In July 2017, there was NDMA in valsartan manufactured with the zinc chloride process. That was a correct statement, right?
MR. BERNARDO: I'm sorry, Adam. Can you repeat?
BY MR. SLATER:
Q. Let me ask it differently. Let me ask it differently.
In July of 2017, there was NDMA in the valsartan manufactured by ZHP. That's a correct statement, right?
A. To the best of my recollection, I have already responded to that question just now.
Q. In July of 2017, it was true that the NDMA in the valsartan was occurring

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when the valsartan was quenched with sodium nitrite during the manufacturing process. That's a true, correct statement, right?

A. You cannot put it that way. I don't think it is a correct statement.

Q. Well, how was the NDMA being formed in the valsartan if it wasn't being formed when the product was being quenched with sodium nitrite? How was it happening if that wasn't the way it was occurring? Please tell me.

A. Let me go back to your previous question. Maybe that was due to the difference between Chinese and English, and something must have lost -- might have been lost in the translation.

I agree that there was NDMA in the valsartan that we manufactured using the zinc chloride-sodium nitrite manufacturing process in 2017.

In fact, there was NDMA in valsartan that was manufactured using the same manufacturing process in 2011. That was the result of our discovery in 2018.

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Q. And the true and correct fact that there was NDMA in valsartan and it was occurring when the valsartan was quenched with sodium nitrite during the manufacturing process, those true and correct facts were made known to you and everybody that received this e-mail in July of 2017, including but not limited to Peng Dong, Linda Lin, and Min Li, and yourself, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That is incorrect. Actually, in July 2017, people, including Jinsheng Lin and others, including the people that I just mentioned, such as Peng Dong, Linda Lin, Min Li, and I, none of us was aware of the existence of NDMA in valsartan, while the reason being in 2017 we did not have the corresponding analytical methods to test out NDMA; therefore, nobody was aware of its existence.

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BY MR. SLATER:

Q. Let's look at the e-mail. Right underneath the little pictures there's a paragraph that says, "In order to further verify the structure of the impurity and its formation mechanism, we plan to simulate the quenching conditions and use the finished Irbesartan product to react with NaNO2" -- which is sodium nitrite -- "and HCl to monitor the impurity produced by the reaction, and then separate it for NMR for final structural verification, while simultaneously carrying out the confirmation of the impurity by multi-stage MS," which means mass spectrometry, correct?

And that's the method that's used to identify NDMA in valsartan, correct?

MR. BERNARDO: Object to the form.

BY MR. SLATER:

Q. Mass spectrometry, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That is

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completely incorrect.

BY MR. SLATER:

Q. Okay. So you don't use mass spectrometry to identify NDMA in valsartan? That's not how it was done?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: As I mentioned earlier, in order to identify an impurity, we have to find out the identity of the impurity first, and then develop analytical methods.

Over here the impurity was referring to the impurity found during the technical improvement of irbesartan on page 1; therefore, the followup work was referring to that impurity, and the confirmation of the structure of that impurity would be done through mass spectrometry.

Once again, the impurity here is regarding the one that was discovered during the technical improvement of irbesartan. He didn't

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say anything about the confirmation of the existence of NDMA. That is my first point.

My second point is that at that time we did not have the right analytical method to identify NDMA in valsartan; therefore, at that time none of us was aware of the existence of NDMA in valsartan.

BY MR. SLATER:

Q. As you said, the first thing you need to do is figure out what impurity you're looking for, and we know that it says right in this e-mail there was NDMA in the valsartan that occurred when it was quenched with sodium nitrite.

So isn't the point that your company already had mass spectrometry available and had already figured out there was NDMA in the valsartan before this e-mail was ever written about this irbesartan project? That's the point, isn't it?

MR. BERNARDO: Object to the form of the question.

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THE WITNESS: Of course that was not the point. If you look at the whole body of this e-mail, I have to say sure enough, this e-mail was so poorly written, and you could not simplify the e-mail by looking at only one sentence. Even the paragraphs written here were very confusing.

At that time, not only Jinsheng Lin himself, even us, did not know anything about the existence of NDMA in valsartan. That was because there was no analytical method would identify NDMA in valsartan. That was my first point.

My second point is that had we known there was NDMA in valsartan at that time, we would have taken the same actions that we took in June 2018.

MR. BERNARDO: Adam, when you're at a point to take a break, we've been going for about an hour and 20 minutes, and it's late.

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MR. SLATER: We can take a break.

MR. BERNARDO: Okay. Let's do that.

THE VIDEOGRAPHER: The time right now is 11:26 a.m. We're off the record.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: The time right now is 11:44 a.m. We're back on the record.

MR. BERNARDO: I just want to point out that Mr. Slater and I were just discussing the scheduling, and it's ZHP's position that we've already reduced the number of topics through stipulations that we've provided by two, so we're only remaining with three topics. So surely we should be able to get this done stopping at midnight, which is reasonable tonight, and doing the same thing tomorrow.

Both Ms. Brown and I, and I

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know Mr. Slater as well, are just getting over COVID, and I really -- while I normally would be willing to go later, I really don't want to overdo it, and I would suggest we go until midnight.

I'm not going to stop you in the middle of a question; if it goes like ten minutes or something over, that's fine.

But we're just not comfortable, for the reasons I just said, going further. And we'll obviously work with you to make sure we can get through this deposition, but I don't see why we can't complete it in tonight and tomorrow night in the time we just discussed.

MR. SLATER: All right. I'm not going to -- probably -- probably not too much benefit for us debating too much over this, but my position is we have a certain amount of time to take this deposition. I'm not going

to start recasting the time that we had.

There was never any discussion when we reached -- when you agreed to admit to certain facts, there was no discussion of limiting the time in a deposition, nor would I ever have agreed to that, nor was it ever raised. So I think that that's a little bit artificial.

Let's hope that we can do well tonight and tomorrow, but we have over 12 hours of time by order. I argued the issue, and the whole point was so we wouldn't be put in a situation where we would be running out of time and start getting into double-time.

So I'm just saying we've only been on the record for three hours and 49 minutes. I'm willing to keep going, and maybe we should start earlier tomorrow night.

MR. BERNARDO: Well, when we're done, let's ask the witness, because

it's obviously 7:00 a.m. her time.

MR. SLATER: She looks like an early riser.

MR. BERNARDO: Sorry, I didn't hear.

MR. SLATER: She looks like an early riser.

MR. BERNARDO: We'll talk afterwards.

MR. SLATER: Okay.

Are we back on?

THE VIDEOGRAPHER: We are on.

MR. SLATER: Okay.

BY MR. SLATER:

Q. Looking at the e-mail from Jinsheng Lin, where he says there's NDMA in the valsartan that occurs when it's quenched with sodium nitrite, he doesn't refer to the patent at all when he says that. The patent comes later, at the end of the e-mail, in a different context, correct?

A. That's incorrect. Actually, as we have discussed in our prior testimony -- in my prior testimony, this e-mail was very

confusing and it was actually quite messy, and it was very hard to understand what it tried to say.

For this e-mail, the -- it didn't say that it was aware of the valsartan impurity at that time. So that's the first thing I wanted to express.

My second point is that at that time Dr. Lin did not become aware of the existence of NDMA in valsartan. That's the feedback he gave me through our communication.

At that time, he was not familiar with any impurity in valsartan. He was not in charge of this product, so his understanding of the impurity in valsartan was only limited to this patent.

As to NDMA as an impurity in valsartan, as in my prior statement, at that time we needed a proper analytical method to identify NDMA in valsartan. However, we didn't have such analytical method; therefore, neither did Jinsheng Lin or we had any knowledge of the existence of NDMA in

valsartan.

Once again, this e-mail was written in such a messy way, and that's the reason why it was very confusing.

Q. Let's look at a few things that are stated in this e-mail.

One of the things in the last paragraph -- rephrase.

The last paragraph states in part that the patent pointed out that the use of sodium nitrite quenching will result in the formation of N-nitroso impurities.

That's one of the things that is stated, correct?

A. That is correct. That's what the patent said. He was basically summarizing what the patent said.

Q. He also says with regard to the patent that this other company "used ZHP's crude Valsartan in their LC-MS test and detected this impurity," which was an N-nitroso impurity, correct?

A. That's what the e-mail says. However, through communication with Dr. Lin,

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he told me that he heard that from a friend of his. However, the other party did not provide any chromatogram as well as data, so he only recited or mentioned that he heard.

Q. He then says in this paragraph that "This indicates" -- meaning what is written in the patent -- "that other companies have paid attention to the quality problem very early on."

So he's referring to this formation of N-nitroso impurities due to sodium nitrite quenching as a quality problem. That's what it says on the document, correct?

A. Your statement is incorrect. In the e-mail, he did refer to the 2013 patent. He also mentioned what he heard from a friend of his regarding Impurity K.

But the e-mail also told us that if, indeed, this Impurity K is a nitroso compound, as it said, then it would become a quality issue. And I agree with that.

Q. Who is this friend that Jinsheng Lin spoke to? What's that person's

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name?

A. He didn't disclose that friend's name in our communication. After all, it's part of the trade secret, you know, in business, and I was shy of prying for such information.

Nevertheless, even after our company heard what he heard from the friend, we paid attention to this issue.

Q. Dr. Lin referred to the use of sodium nitrite quenching resulting from the formation of N-nitroso impurities as a quality problem, correct?

A. I don't quite get your question. However, I'll try to respond.

In this e-mail, he did mention the Impurity K referred to in the patent. If this Impurity K is indeed a nitroso compound, then we have to control this impurity. That's from the perspective of FDA as well as the perspective of GMP. We have to control this impurity.

If, after confirmation, we have confirmed or identified this Impurity K in

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our product, then indeed this would be regarded as a quality issue, a quality problem.

Q. If you had detected NDMA in valsartan, that would be a quality problem, too, right?

A. Definitely. At that time we didn't have the analytical method to detect the NDMA in valsartan. Otherwise, we wouldn't have been sitting here for this deposition, right?

Q. He finishes that paragraph at the end of this e-mail and says, "So leaders please pay attention to this issue." Right? That's what he said?

A. That is correct.

Q. So let's be clear. In this e-mail, Jinsheng Lin said in an e-mail that went to you, who -- you were the head of quality at the time, is that correct?

A. I was the QA head at Chuannan site, yes.

Q. It went to you; it went to Min Li, who was the head of CEMAT; it went to

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Peng Dong; it went to Linda Lin, the head of regulatory, and some other people.

And in this e-mail, he said that there was NDMA in valsartan that occurred when it was quenched with sodium nitrite.

He talked about a patent that he read that said that the use of sodium nitrite quenching will result in the formation of N-nitroso impurities.

He pointed out that this would be a quality problem, and he also said the way to detect this impurity would be with liquid chromatography-mass spectrometry, and told the leaders to pay attention to this issue. So all that information was there.

You and everyone on that e-mail knew that you were quenching the valsartan with sodium nitrite, yet it's your testimony that nobody in response to this e-mail actually said, Let's use the liquid chromatography-mass spectrometry machine at CEMAT -- which was an Agilent, A-G-I-L-E-N-T, 6100 single quad LC-MS machine -- and let's

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try to identify whether there's nitrosamines in our valsartan.

Do I have that correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That's completely incorrect. Look at the title of this e-mail. It was about the impurity that generated from the sodium azide quenching in the technical improvement of irbesartan.

For this impurity, this e-mail was actually the investigation report. It is all about irbesartan.

So while he was searching for this nitroso impurity, he found this patent regarding valsartan, which mentioned Impurity K. And he was trying to make a comparison between that impurity from irbesartan and Impurity K as well as NDMA in toxicology.

In the end of the e-mail, he did mention that could be a quality

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issue, because for valsartan that could be Impurity K, which was already found by an analysis done by other companies. So he asked all the leaders to pay attention, which we did.

I don't know why you interpret the e-mail this way. As in the large volume of discussion we had before, in 2017 Jinsheng Lin, Min Li, or any of us did not know the existence of NDMA in valsartan.

There are so many reasons why we were not aware of that, one of them being that we did not have the analytical method to identify and detect the NDMA in valsartan. We were not aware of such thing, so how could we come up with the analytical method such as LC-MS for any unknown impurity? How could we make up any analytical method for that?

So we didn't know what to do. We didn't know what method to develop

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for that impurity, simply because we were not aware of that impurity, not until June 2018 when Novartis made the complaint. And the company was paying full attention to that.

Not only did we develop the analytical method to detect that impurity; we also reported that to FDA, among many other actions we took.

Had we known the existence of NDMA in valsartan in 2017, we would have done the same thing that we did in 2018.

So as you can see here, this report is about the investigation of an impurity in this small-scale technical improvement of irbesartan. And how could we then expand that to an already commercialized product, valsartan, for the suspicion that there might be NDMA in it?

So out of common sense, this doesn't sound reasonable. Once again, at that time we were not aware of the

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existence of NDMA in valsartan.

BY MR. SLATER:

Q. The e-mail says that the use of sodium nitrite quenching in valsartan will result in the formation of N-nitroso impurities.

So even accepting everything you said about what ZHP didn't know, as of the date of this e-mail, your company was on notice that the sodium nitrite quenching of any of its sartans needed to be investigated and testing needed to be done to see if nitrosamines were being formed, right?

Nothing was done, correct? According to you, nothing was done?

MR. BERNARDO: Objection. Let her answer the first question before you ask the second, please.

THE WITNESS: What's the first question? Your question was super long.

BY MR. SLATER:

Q. I'm not asking the question again. You heard the question; you can

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answer it.
Do you want me to ask a new question? I'll ask a new question. It was objected to; I'm happy to.
So here's the first thing. After this e-mail was sent, no testing was done of any of your sartans to determine whether N-nitroso compounds were being formed due to the sodium nitrite quenching, is that your testimony?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: It's not correct. You cannot put it in that way.
Over here we talked about the Impurity K, because the patent mentioned Impurity K. And also other companies found Impurity K in the analysis of our crude products.
We actually care about the impurity in our finished products; therefore, after communication I found that not only Jinsheng Lin, but also Peng Dong, did analysis of Impurity K

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and couldn't find any Impurity K.
So we did pay attention to this issue and took actions. You cannot say we never conducted any testing.
BY MR. SLATER:
Q. You're saying that Jinsheng Lin and Peng Dong in 2017 tested valsartan to see if there was Impurity K in it?
A. It went like this. During the communication with Jinsheng Lin, he told me he did conduct analysis of Impurity K in 2017.
Likewise, I also communicated with Peng Dong, and he also conducted an analysis regarding Impurity K in our product. And he also received the feedback from CEMAT that CEMAT did not find any Impurity K in our product.
Q. What CEMAT did find was NDMA in the valsartan, and that's why Jinsheng Lin said it in his e-mail, that there's NDMA in the valsartan that's caused when it's quenched with sodium nitrite.
That is what was found, right?

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MR. BERNARDO: Object to the form of the question. Characterization of the prior testimony.
THE WITNESS: That's completely incorrect.
As I stated in my prior testimony, Jinsheng Lin or any of the other people on this e-mail was not aware of the existence of NDMA in valsartan, because at that time there was no such analytical method to identify NDMA in valsartan. So your statement is completely incorrect.
BY MR. SLATER:
Q. You're -- rephrase.
So you're testifying that when Jinsheng Lin said there was NDMA in valsartan, he said that for no reason, and it was just a complete coincidence and lucky guess?
Is that your testimony?
MR. BERNARDO: Object to the form of the question.

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THE WITNESS: Your statement is completely incorrect, as I stated in my prior testimony.
At that time Jinsheng Lin was not aware of the existence of NDMA in valsartan. His understanding of NDMA in valsartan was only limited to that patent.
I also stated that this e-mail, in terms of what it tried to state, was written in such a messy and ambiguous way.
And in this e-mail, he was trying to make a comparison between NDMA and that impurity he found in toxicology. So the e-mail did not acknowledge that he already had the awareness of NDMA in valsartan. And none of us did, the reason being there was no analytical method to identify such an impurity.
Without such an analytical method to identify the impurity in the testing, how can we come up with such

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knowledge? Therefore, I believe your statement is completely incorrect.

In order to fully understand this e-mail, I also mentioned before that you need to read the context of the e-mail or the entirety of this e-mail, as well as the attachment to it.

BY MR. SLATER:

Q. The patent does not mention NDMA, correct?

A. That is correct. The patent did not mention NDMA in its entirety.

Q. Jinsheng Lin did reference NDMA in valsartan in his e-mail, correct?

A. I already mentioned that in terms of the reference of NDMA, at the time he was only trying to make a comparison in toxicology between NDMA and the impurity he found regarding the irbesartan.

The patent did not mention NDMA. However, the patent mentioned that when valsartan was quenched with sodium nitrite, there was an -- an impurity came.

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That is the evidence that at that time the whole industry, ZHP, or Jinsheng Lin did not have the awareness of NDMA in valsartan. Otherwise, the patent would have mentioned NDMA instead of Impurity K.

Q. When you say that there was not an analytical method to identify NDMA in the valsartan, you're not saying that it wasn't technologically feasible to do it, right? You're not claiming that there was no such method in the world to do that, are you?

A. As I mentioned before, when you try to develop an analytical method for a specific impurity, you have to do that development regarding that impurity.

I listed two FDA announcements or documents. Judging from the content of such documents, you could tell that first you have to be aware of such an impurity. Then you would develop an analytical method targeting that impurity.

Q. And that was technologically feasible in 2011 through 2018, right?

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MR. BERNARDO: Object to the form of the question.

THE WITNESS: I don't know what you mean by "technologically feasible." Can you be more specific?

BY MR. SLATER:

Q. The technology and the scientific knowledge existed so that if one at ZHP wanted to develop a method to try to identify NDMA in valsartan, that could be done, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: Had we known prior to June 2018 that there was an impurity called NDMA, I believe my company would have been capable of developing such an analytical method for this impurity, just like what we did when we became aware of such an impurity in June 2018.

MR. BERNARDO: Adam, I'm trying to be cooperative. We went a half-hour longer than we had

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anticipated. And if we can end it here, I'm happy to go off the record and ask Ms. Ge if she's willing to start early tomorrow as well. But I'd like to stop here.

MR. SLATER: Well, I'm going to be a gentleman and I'm not going to argue with you. I've already told you how I feel about it. I'm prepared to keep going, but I understand your position, and I'm going to try to be optimistic that despite my disappointment in not getting to go into the deep of night, that we'll be able to finish this deposition tomorrow night and not ruin everybody's Friday night before Memorial Day.

MR. BERNARDO: I would point out we are in the deep of the night, but other than that, I appreciate that.

Why don't we go off the record and see if Ms. Ge is willing to start

earlier tomorrow.

THE VIDEOGRAPHER: The time right now is 12:32 p.m. We're off the record.

(Whereupon, the deposition was adjourned.)

CERTIFICATE

I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, JUCAI GE, was remotely duly identified and sworn by me to testify to the truth, the whole truth, and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

____

MAUREEN O'CONNOR POLLARD
NCRA Registered Diplomate Reporter
Realtime Systems Administrator
Certified Shorthand Reporter
Notary Public

Dated: June 2, 2022

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

E R R A T A

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ACKNOWLEDGMENT OF DEPONENT

I, ___________________________, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
WITNESS NAME DATE

Subscribed and sworn
To before me this
_______ day of __________________, 20____.

My commission expires: _________________

____
Notary Public

LAWYER'S NOTES

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